Performance Measurement Evaluation for the Risk Management of Dichloromethane (DCM) / Methylene Chloride

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Executive summary

This report measures and evaluates the performance of risk management actions taken to protect Canadians from dichloromethane (also known as methylene chloride, or DCM) exposures that were found to pose a risk to human health. Dichloromethane was selected for performance measurement evaluation because key baseline and performance indicator data are available, and human health risk management actions have been in place for a sufficient amount of time to measure impact.

Dichloromethane was first assessed by the Government of Canada in 1993, where it was found to be a concern to human health and the environment. A pollution prevention (P2) plan, and a code of practice were implemented to help reduce environmental exposures of dichloromethane. To reduce dichloromethane exposures to the general population in Canada, risk management actions were established through section 16 of the *Food and Drugs Act* (FDA). One way Health Canada communicated this risk management action was to add dichloromethane to the Department's Cosmetic Ingredient Hotlist (the Hotlist).

Information collected by the Government of Canada shows that since risk management actions came into effect:

- long-term levels of dichloromethane in outdoor air remain below levels of concern
- long-term levels of dichloromethane in indoor air remain below levels of concern and
- notifications for 3 aerosol cosmetic products containing dichloromethane were received – and these products were removed from sale in Canada

Overall, risk management actions are meeting their intended goals, and Canadians have been protected from the potential health risks identified in the 1993 assessment. However, given the concerns with the hazard profile of dichloromethane and that the human health objective from the Priority Substances List (PSL) assessment was to 'reduce exposure to dichloromethane wherever possible', more work needs to be done to assess the acute risks associated with the use of products containing dichloromethane, as this

has been identified as a concern internationally, which has not been fully accounted for in this review. Dichloromethane has been prioritized for further risk assessment work, and should additional risks be identified, further risk management actions may be implemented.

1. About performance measurement

The Government of Canada is conducting a performance measurement evaluation on the risk management of toxic substances to ascertain whether actions taken to help protect Canadians and their environment are meaningful and effective over time. Performance measurement evaluation will help determine how well the risk management actions have reduced or eliminated the risk associated with each substance concluded to be toxic under the *Canadian Environmental Protection Act,1999* (CEPA). Adjustments may be required when risk management actions are not achieving the desired outcome.

The Government of Canada establishes goals in order to help protect Canadians and their environment from risks posed by toxic substances. The Government aims to achieve these goals by setting human health, environmental and/or risk management objectives, and developing a strategy to meet those objectives. Performance measurement evaluation assesses how risk management actions contribute to protecting Canadians from toxic substances, and identifies any areas of improvement, or whether risk management strategies need to be updated or adapted.

2. Background

Dichloromethane (DCM, also known as methylene chloride and "Methane, dichloro" with CAS# 75-09-2) is a colourless, volatile organic liquid that does not occur naturally. It is soluble in most organic solvents, and has a high evaporation rate. These properties make dichloromethane a versatile substance, and it is used in a wide variety of applications including as a solvent in paint and furniture stripping products, a blowing agent in foam production, as a component in aerosol products, and in other industrial process applications. Dichloromethane is not currently manufactured in Canada, but is imported (Statistics Canada, 2021).

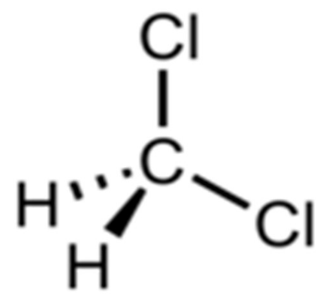

Figure 1. The chemical structure of dichloromethane

Dichloromethane is currently classified as a probable carcinogen to humans (Group 2a) by the International Agency for Research on Cancer (IARC), based on limited evidence in humans and sufficient evidence in experimental animals (IARC, 2017). Non-cancer effects on the liver have also been associated with long-term exposure to dichloromethane in humans (Government of Canada, 1993; Health Canada, 2011; U.S. Environmental Protection Agency, 2011; Schlosser et al., 2015). Acute exposure via inhalation of high concentrations of dichloromethane over a very short period of time can lead to serious effects on the central nervous system, which can lead to death (Rioux & Myers, 1988; U.S. Environmental Protection Agency, 2011).

Dichloromethane was assessed in Canada and a PSL Assessment Report was published in 1993 (Government of Canada, 1993). Human exposure to dichloromethane through ambient air, indoor air, drinking water, and food were quantified, and indoor air was estimated to be responsible for greater than 90% of dichloromethane exposures among Canadians of all age groups (Government of Canada, 1993).

Concerns of occupational exposures and of acute exposures from products available to consumers were not examined in the 1993 risk assessment. Although there is no comprehensive data source on the occurrence of adverse health events due to acute exposure to dichloromethane in Canada, there have been reports of serious adverse health events among workers occurring in Canada, including a serious workplace incident that occurred in Manitoba in 2019 (SAFE Work Manitoba, 2019). There have also been such occurrences in other countries like the U.S. (where there is a similar availability of products available to consumers). For instance, there were 589 cases of dichloromethane poisonings in the U.S. in

2018 according to the American Association of Poison Control Centers (Gummin et al., 2019). Two hundred and twenty (37%) of these cases needed to be treated in a health care facility, and 1 case was fatal (Gummin et al., 2019). In total, there were an estimated 85 dichloromethane-related fatalities in the U.S. between 1980 to 2018, of which 11 (13%) occurred outside occupational settings (Hoang et al., 2021). The U.S. Environmental Protection Agency (EPA) published an assessment of dichloromethane in 2020 and found unreasonable risk for 32 out of 33 industrial and commercial use scenarios, and for all 12 consumer use scenarios (United States Environmental Protection Agency, 2020).

Dichloromethane was selected for performance measurement and evaluation because there is adequate performance indicator data with which to inform a comprehensive evaluation of management of risks linked to human health, because sufficient time has passed since human health risk management actions were taken, and because of recent risk management action by other jurisdictions concerning acute exposure concerns from products available to consumers (United States Environmental Protection Agency, 2020).

3. Risk management approaches

To help address both the human health and environmental concerns that were identified in the PSL assessment, 3 risk management actions were undertaken by the Government of Canada to help reduce environmental emissions and human exposures to dichloromethane: addition to the Hotlist, a P2 plan, and a code of practice. Further, consumer chemical products that contain dichloromethane are subject to *Consumer Chemicals and Containers Regulations, 2001* (CCCR, 2001). This means that these products are required to follow labelling for toxicity and packaging requirements depending on their classified short-term exposure risks. A summary of the stakeholder consultations on these options was published in 1998 (Environment Canada, 1998).

3.1 Addition to the Hotlist for aerosol cosmetics (1995)

The Government of Canada took action to help prevent deliberate use of dichloromethane in aerosol cosmetic products by describing the substance as a restricted ingredient on the Health Canada Hotlist since 1995. Using this administrative tool, Health Canada informs manufacturers and others that an aerosol cosmetic product that includes dichloromethane as an ingredient may contravene section 16 of the FDA. Compliance with the FDA section 16 is monitored, in part, through the mandatory notification provisions of section 30 of the *Cosmetic Regulations*. Therefore, for each cosmetic sold in Canada, the cosmetic's manufacturers and importers are required to provide Health Canada with, among other things, a list of the product's ingredients and the ingredients' exact concentration or their concentration range.

3.2 P2 Plan (2003)

P2 plans are risk management tools published in the *Canada Gazette* under Part 4 of CEPA that require persons subject to the notice to prepare and implement a P2 plan in respect of a specified substance.

The P2 planning notice for dichloromethane was published in December 2001 for consultation, and the notice for the implementation was published in November 2003. Five sectors were subject to the P2 plan:

- Adhesives formulation
- Aircraft paint stripping, including stripping of aircraft components
- Flexible polyurethane foam blowing
- Industrial cleaning and
- Pharmaceuticals and chemical intermediates manufacturing and tablet coating

The risk management objective was to "reduce aggregate dichloromethane releases from 5 targeted industry sectors by 85% from 1995 base year levels by January 1, 2007". Each industry also had individual risk management objectives for releases, pollution prevention techniques, and/or uses of dichloromethane.

The outcomes and performance of this P2 plan were evaluated in 2010 (Government of Canada, 2010). While overall the P2 plan was deemed a success due to exceeding its target reduction in emissions (93% realized vs 85% target), 3 of the 5 sectors (adhesives formulation; aircraft pain stripping, including the stripping of aircraft components; and pharmaceuticals and chemical intermediates manufacturing and tablet coating) did not meet their individual industry objective.

3.3 Code of Practice for paint strippers in commercial furniture refinishing and other stripping applications (2003)

Environmental codes of practice are voluntary instruments under CEPA that the Minister of the Environment and Climate Change can use to recommend procedures, practices, or environmental controls in the activities relating to substances including toxic substances. Among other things, a code of practice can set out official national standards that companies and organizations should follow.

The code of practice implemented for dichloromethane was aimed at commercial activities involving its use in commercial paint stripping applications (Government of Canada, 2003). While the main objective was to reduce emissions of dichloromethane into the environment, the code also states that by reducing environmental emissions of dichloromethane, human exposures might also be reduced. To accomplish this, the code provides information on best practices in the application and use of dichloromethane in several different applications relevant to commercial furniture restoration facilities, as well as miscellaneous commercial paint stripping facilities (such as metal parts paint strippers, auto body shops, and building restorers).

It was projected that the implementation of the code of practice, commercial uses of dichloromethane (and subsequently, the amount released to the environment) could be reduced by 20% (Government of Canada, 2003).

4. Performance measurement indicators

In this performance measurement evaluation report, indicators that provide trending information on exposures to Canadians were used to evaluate the effectiveness of risk management actions. As the human health objective of dichloromethane was the "reduction of exposure to dichloromethane wherever possible", this includes exposure sources that may not have been identified in the original PSL assessment. Indicators have been classified into 2 categories: exposures from products available to consumers, and environmental exposures.

4.1 Exposures from products that contain dichloromethane

4.1.1 Cosmetic notifications

Manufacturers and importers of cosmetic products must notify Health Canada within 10 days after they first sell a cosmetic in Canada, as per section 30 of the *Cosmetic Regulations*. Whenever a change in the information on the notification occurs, an amended cosmetic notification must be submitted. These notifications require information including the form of the cosmetic (aerosol, foam, liquid, etc.), a list of the product ingredients, and the ingredients' concentrations. Data from notifications received by Health Canada was used to assess the effectiveness of the FDA section 16 with respect to dichloromethane.

4.1.2 Safety Data Sheets (SDS) for products containing dichloromethane

Consumer products that contain dichloromethane are an exposure source that was not considered in the PSL assessment, and therefore were not specifically addressed within existing risk management activities. Current and historical market data on products containing dichloromethane that are available to consumers were not available. A database of SDS, created by obtaining SDS for products listed on the websites of 2 large national retailers, was used. As this database was established in 2014 and does not include historical chemical products available to consumers that may have been available for sale prior to this database being established, trends over time cannot be reliably established.

4.2 Environmental exposures

4.2.1 Industrial emissions – National Pollutant Release Inventory (NPRI)

As dichloromethane is a substance that does not occur naturally, and is emitted primarily from industrial processes, the quantity of this substance released to the environment from facilities provides an accurate estimate of the amount of dichloromethane being released to ambient air, where Canadians may inhale it. The NPRI is Canada's legislated, publicly accessible inventory of pollutant releases (to air, water, and land), disposals and transfers from industrial, commercial and institutional facilities. It collects information on more than 320 substances from over 7,000 reporting facilities. The inventory data provides a Canada-wide and facility-specific emissions perspective. Emissions of dichloromethane have been reported since 1993. Any facility that manufactured, processed or otherwise used at least 10 tonnes of dichloromethane and had more than 20,000 employee hours in a calendar year is obligated to report their emissions.

A decrease in the reported emissions to air could indicate the effectiveness of the risk management actions. As stakeholders were originally consulted in 1996 on possible risk management options for dichloromethane, it is important to note that decreases in reported emissions may be seen before the actual publication date of the P2 planning notice in November 2003 (Environment Canada, 1998).

4.2.2 Ambient air concentrations – National Air Pollution Surveillance (NAPS)

The P2 planning notice and the code of practice implemented in 2003 were both expected to result in a reduction in the quantity of dichloromethane in outdoor air by reducing the amount of dichloromethane emitted by the targeted sectors.

The NAPS program provides accurate and long-term air quality data of a uniform standard across Canada. NAPS is managed using a cooperative agreement among the provinces, territories and municipal governments. Ambient air levels of dichloromethane have been measured by the NAPS network of monitors since 1989. Data collected, compiled and analyzed by this program provides the government and Canadians with information about dichloromethane concentrations at many different sites across the country.

The effects of the P2 planning notice and the code of practice on reducing emissions of certain industries would be expected to result in the reduction of dichloromethane measured in ambient air, particularly in locations close to the impacted facilities. Small fluctuations in measured concentrations from year to year may be a result of the fact that the number and location of NAPS monitors used in the calculations was not constant. To help ensure estimates are stable, only stations with at least 40 samples in a given year are included in the annual averages, although the timing of sampling and of the activity of nearby industries are factors that may introduce variability.

4.2.3 Indoor air data – Health Canada's indoor air studies

The concentration of dichloromethane in indoor air was identified as the greatest source of dichloromethane exposure in the original PSL assessment in 1993 (Government of Canada, 1993).

Health Canada has conducted several studies that investigated indoor air quality in homes in cities across Canada. Data from studies conducted in Windsor in 2005 to 2006 (Health Canada, 2010b), Regina in 2007 (Health Canada, 2010a), Halifax in 2009 (Health Canada, 2012), and Edmonton in 2010 (Health Canada, 2013) can be used to estimate levels of dichloromethane in Canadian homes.

In addition to the PSL report (Government of Canada, 1993) and the drinking water guideline (Health Canada, 2011), Health Canada has also derived an Indoor Air Reference Level (IARL) for dichloromethane. To develop an IARL, Health Canada evaluates assessments from internationally recognized health and environmental organizations, and selects the most appropriate previously-derived reference level for Canadian homes. The IARLs represent concentrations that are associated with acceptable levels of risk following long-term exposure, as determined by the organization that performed the risk assessment. Health Canada's IARL for dichloromethane is 600 $\mu g/m^3$, and is based on the U.S. EPA Integrated Risk Information System (IRIS) reference concentration (RfC), which was derived for non-cancer liver (U.S. Environmental Protection Agency, 2011).

5. Available data

5.1 Exposures from products that contain dichloromethane

5.1.1 Cosmetic notifications

Prior to 2012, no notifications were received for aerosol cosmetics that contained dichloromethane as an ingredient, suggesting that such products were unavailable to be purchased within Canada. Between 2012 to 2018, 3 aerosol cosmetics products with dichloromethane indicated as an ingredient were notified and had a concentration of concern described on Health Canada's Hotlist. Industry voluntarily stopped selling products 1 and 2 in Canada within 5 months of Health Canada receiving the products' notification forms. A notification for the third product indicated that industry reformulated it to no longer contain dichloromethane 12 months after initial notification. There were <100 units of Product 2 and Product 3 sold before being voluntarily recalled by the regulated party. Information on quantity of Product 1 was not available. This suggests that the Hotlist has limited exposures to Canadians through cosmetic products to relatively low levels.

5.1.2 SDS for chemical products containing dichloromethane

There were a total of 155 relevant SDS retrieved for products containing dichloromethane from 2004 to 2018. For each product, the SDS includes the product name, its intended use, the date the SDS was prepared or amended, and the lower and upper ranges of dichloromethane concentration. Ranges of concentrations for components can be included on SDS pages per the *Hazardous Products Regulations*. In order to standardize the different products, a midpoint concentration of dichloromethane was obtained by averaging the lower and upper limits on each of the SDS pages.

Products were then grouped together into broad categories based on the advertised use of the product and the average of the lower limit, midpoint, and upper limit of all the products in a category was obtained, shown in Figure 2. The numbers directly above each category name represent the number of products within the category. Products that were classified as shoe cleaners, furniture strippers, paint removers, and adhesive removers all had an average midpoint concentration of dichloromethane of approximately 75% to 85%. Meanwhile, lubricants, cleaners, coatings and sealants had concentrations that ranged between 12% to 40% dichloromethane. The refrigerant class of products only contained trace amounts of dichloromethane (<1%).

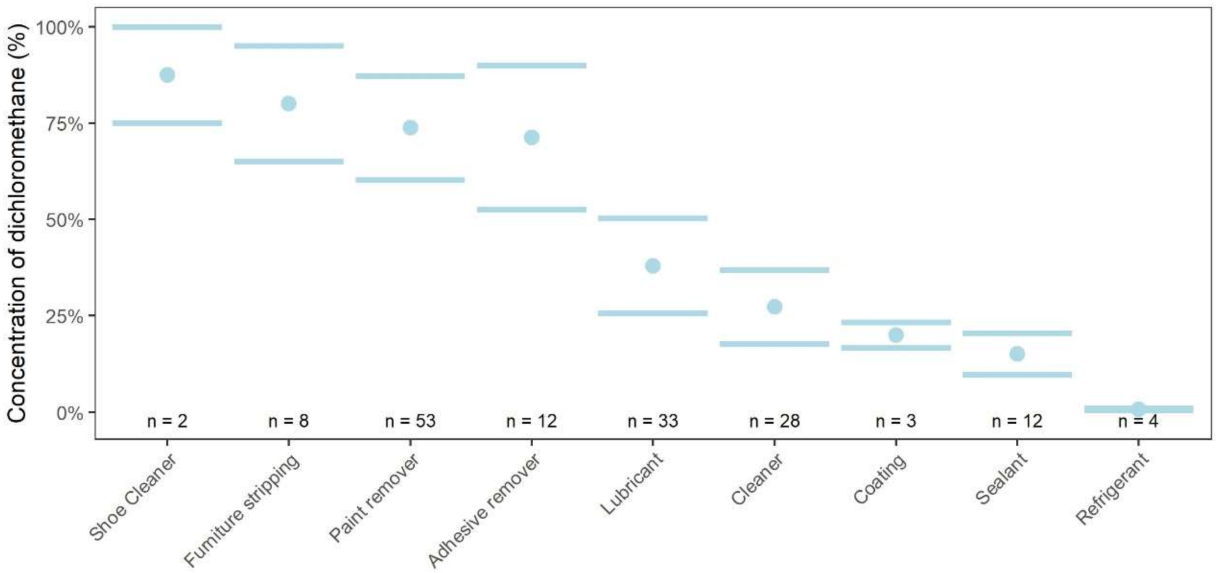

Figure 2. Average of lower, midpoint, and upper dichloromethane concentrations listed on safety data sheets, by category. Values above the x axis show the number of products that were used in the calculation of each category’s average concentration.

5.2 Environmental exposures

5.2.1 Industrial emissions – NPRI

The total annual emissions of dichloromethane to air from 1994 – 2019 by facilities reporting to NPRI are shown in Figure 3. Total emissions to air in 2019 totaled 20 tonnes, down 99.1% from the amount emitted in 1995 (2314 tonnes) which was the base year of the P2 planning notice. This includes a reduction of 1062 tonnes since 2002, the year directly following the P2 planning notice consultation, and a reduction of 506 tonnes since 2004, the year directly following the implementation of the P2 plan and the code of practice.

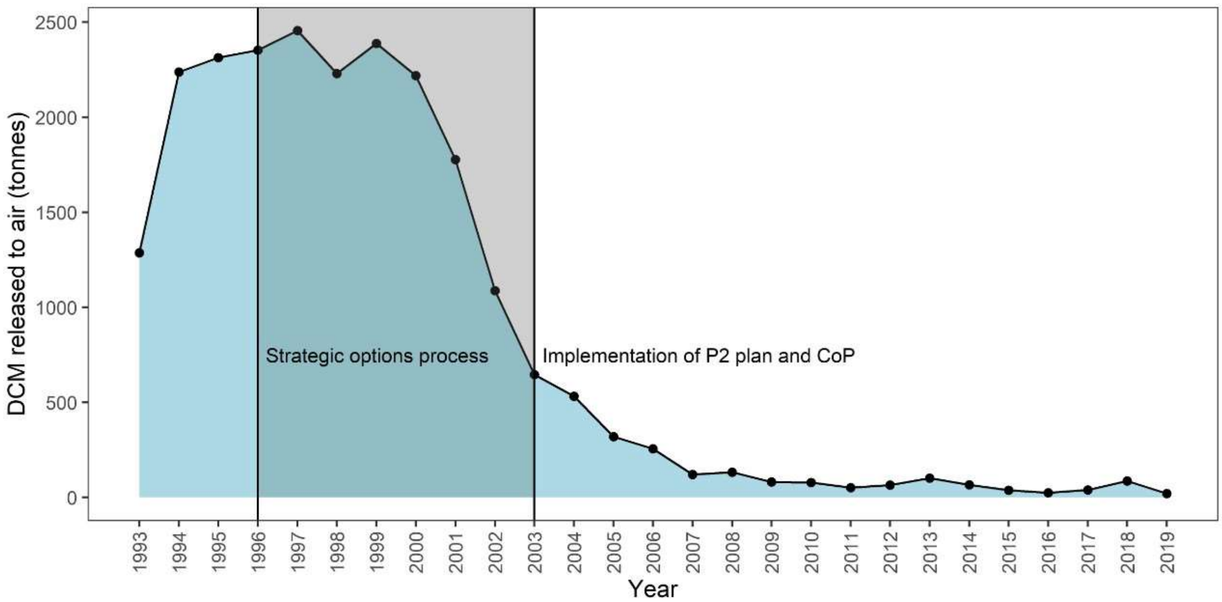

Figure 3. Annual total dichloromethane releases to air reported to NPRI between 1993 and 2019.

5.2.2 Ambient air concentrations – NAPS

Data collected from NAPS monitors from 1989-2019 are shown in Figure 4. Ambient concentrations of dichloromethane decreased from 0.86 µg/m^3 in 1995 (the reference year for the P2 planning notice) to 0.60 µg/m^3 in 2019, a reduction of 30%. While concentrations have largely remained stable since 2004, there was a slight increase in concentrations measured between 2016 and 2017, due to the introduction of a new NAPS monitor located close to facilities emitting dichloromethane, though observations from more recent years have shown a return to a decreasing trend. While a national guideline on safe levels of dichloromethane in outdoor air have not been established, the province of Ontario has set an Ontario Ambient Air Quality Criteria limit of 44 µg/m^3 for annual exposures to dichloromethane, while the province of Quebec has set an annual limit of 3.6 µg/m^3. All observed concentrations are well below these limits.

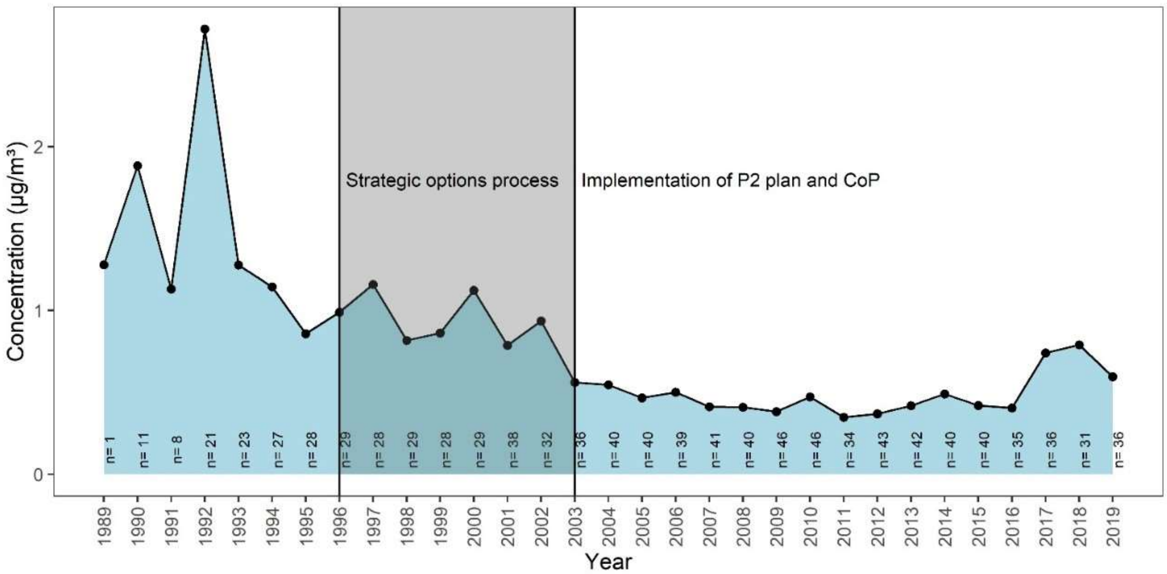

Figure 4. Average ambient air concentrations of dichloromethane obtained from NAPS monitors, between 1989 and 2019. Values above the x axis show the number of stations that were used in the calculation of each year's average concentration.

5.2.3 Indoor air data – Health Canada indoor air studies

In the original PSL assessment report, the mean concentration of dichloromethane in indoor air was 16.3 µg/m^{3}. This was based on preliminary data from a 1992 study that surveyed the air inside 757 Canadian homes (Government of Canada, 1993). Since the P2 plan and code of practice were implemented in 2003, Health Canada indoor air studies have been conducted in several cities across Canada including Windsor in 2005 and 2006, Regina in 2007, Halifax in 2009, and Edmonton in 2010. The median concentration of dichloromethane ranged from 0.46 – 1.48 µg/m^{3} and the highest detected value from all the studies was 389 µg/m^{3}, below the IARL of 600 µg/m^{3}. A study of indoor air in 96 homes in Quebec city in 2005 found a median value of 7.04 µg/m^{3} (Héroux et al., 2008). A maximum value of 1687 µg/m^{3} was reported in one home, in excess of the IARL, but this could have been due to recent use of a product containing dichloromethane, as recent painting was found to be associated with higher levels of dichloromethane in this same study (Héroux et al., 2008). Direct comparisons between the dichloromethane levels found in the 1992 study and the more recent Health Canada studies cannot be made due to differences in experimental design and in location. A summary of the indoor air studies can be found in Supplementary Table 1.

6. Performance measurement evaluation

6.1 Products available to consumers

Review of cosmetic notifications show that 3 aerosol cosmetic products that contained dichloromethane were notified to Health Canada. Industry voluntarily removed these products from the market after Health Canada received the notifications.

For other products containing dichloromethane, the published SDSs show that there are several products with dichloromethane that may be available to consumers.

6.2 Environmental exposures

The quantities of dichloromethane emitted from facilities and measured directly in outdoor air have decreased 99.1% since this substance was assessed in the PSL assessment report of 1993. Outdoor air levels were identified as a small proportion of the overall exposure of dichloromethane in humans, and these levels have remained stable since the P2 plan and code of practice were implemented. Concentrations measured in 2019 (0.60 $\mu g/m^3$) were 30% lower than what was used in the original risk assessment (a range of 0.9 $\mu g/m^3$ - 6.2 $\mu g/m^3$) and continue to make up only a very small proportion of total exposures.

More trending data on long-term indoor air concentrations of dichloromethane in Canada are required to conclude on the impact of risk management measures.

7. Conclusion

Based on the information available, risk management actions taken by the Government of Canada have been successful in reducing the exposures of Canadians to dichloromethane through outdoor air and when using aerosol cosmetic products. The effectiveness of risk management actions on long-term indoor air exposures cannot be conclusively evaluated due to lack of comparable exposure information.

Exposures to dichloromethane in the occupational setting, and from products containing dichloromethane available to consumers were not considered in the PSL assessment (Government of Canada, 1993). Since such exposures have recently been deemed to be of concern in other jurisdictions (United States Environmental Protection Agency, 2020), and there is evidence suggesting that products containing dichloromethane are available to consumers in Canada, there is a need to further characterize the possible risk from these exposures to dichloromethane.

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Appendices

Supplementary Table 1. Summary of the Health Canada indoor air studies.

	Windsor (2005)(Health Canada, 2010b)	**Windsor (2005)**(Health Canada, 2010b)	**Windsor (2006)**(Health Canada, 2010b)	**Windsor (2006)**(Health Canada, 2010b)	**Regina (2007)**(Health Canada, 2010a)	**Regina (2007)**(Health Canada, 2010a)	**Halifax (2009)**(Health Canada, 2012)	**Halifax (2009)**(Health Canada, 2012)	**Edmonton (2010)**(Health Canada, 2013)	**Edmonton (2010)**(Health Canada, 2013)
Season	Summer	Winter	Summer	Winter	Winter	Summer	Winter	Summer	Winter	Summer
Minimum detectable level (MDL, μg/m^3)	0.089	0.089	0.081	0.081	0.024	0.024	0.055	0.055	0.012	0.053
Count (n)	217	232	211	224	105	105	312	331	337	328
Minimum (μg/m^3)	0.265	0.212	0.04	0.17	0.207	0.21	0.203	0.192	0.272	0.247
Maximum (μg/m^3)	79.6	17.02	389.347	130.08	81.183	77.495	156.6	173.2	59.46	7.13
Percent of samples > MDL (%)	100	100	99.5	100	100	100	100	100	100	100
Arithmetic mean (μg/m^3)	5.054	1.956	15.14	4.963	5.425	5.152	6.969	6.854	2.006	0.799
Geometric mean (μg/m^3)	1.63	0.893	2.029	1.238	1.546	1.469	1.448	1.197	0.94	0.627
5th percentile (μg/m^3)	0.405	0.292	0.283	0.247	0.253	0.273	0.253	0.228	0.32	0.27
25th percentile (μg/m^3)	0.665	0.393	0.483	0.387	0.49	0.525	0.412	0.308	0.427	0.349
50th percentile (μg/m^3)	1.015	0.52	1.48	0.695	1.14	1.06	0.802	0.712	0.607	0.464
75th percentile (μg/m^3)	2.83	1.783	4.373	4.532	3.643	2.97	6.472	3.664	1.428	0.925
90th percentile (μg/m^3)	12.547	5.308	22.22	11.33	13.987	10.45	15.73	13.33	3.824	1.704
95th percentile (μg/m^3)	27.06	9.808	49.053	29.627	24.82	27.615	22.24	28.79	7.62	2.324